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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	10

DATE MAILED: 07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/343,406	Endl
Examiner	**Art Unit**
Marianne DiBrino	1644

-- The MAILING DATE of this communication app ars on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Sep 28, 1999, 11/10/99, 6/30/99, 7/9/01

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 46-58 is/are pending in the applica

4a) Of the above, claim(s) 55-58 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 46-54 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Applicant's amendments filed 9/28/99 (Paper No. 6), 11/10/99 (Paper No. 3), 6/30/99 (Paper No. 2) and Applicant's response filed 7/9/01 (Paper No. 9) are acknowledged and have been entered.

Claims 46-58 are pending.

2. Applicant's election without traverse of Invention I (claims 46-54), and species of SEQ ID NO: 2 in Paper No. 9 is acknowledged.

Claims 46-54 read on the elected species, SEQ ID NO: 2.

Upon consideration of the prior art, the search has been extended to include SEQ ID NO: 3 and SEQ ID NO: 19.

Accordingly, claims 55-58 (non-elected Invention II) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 46-54 are currently being examined.

3. Applicants are required under 37 C.F.R. 1.821(d) to amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification (for example, in the Brief Description of the Drawings for Figures 1 and 2).

4. It is noted that this application appears to claim subject matter disclosed in prior copending Application No. 08/967,242 and Application No. 08/374,468, filed 11/5/97 and 1/18/95, respectively. A reference to the prior application must be inserted as the first sentence of the specification of this application if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a).

5. Acknowledgment is made of applicant's claim for foreign priority based on an applications P4403522.5, P4401629.8 and P4418091.8 filed on 2/4/94, 1/20/94 and 5/24/94, respectively. It is noted, however, that applicant has not filed a certified copy of the application as required by 35 U.S.C. 119(b).

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 46-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendatory material that is not supported by the specification and claims as originally filed is as follows: (1) a peptide/peptide derivative of at least 6, 8 or 10 amino acids from one of SEQ ID NO: 19-39 and having at most 25 amino acids and includes anchor positions for binding to DR3 or DR4.

8. Applicant is reminded of the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999; the following rejection is set forth herein.

9. Claims 46-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed: (1) peptide consisting of between 6 and 25 amino acids comprising at least 6 amino acids of an amino acid sequence selected from the group consisting of SEQ ID NO: 2, 3 and 19-39, including those wherein the peptide includes anchor positions for binding to alleles of MHC class II molecules DR3 and DR4, (2) a peptide or derivative thereof with length between 6 and 25 amino acids which exhibits a specificity or/and affinity which is essentially equivalent to that of the peptide in "(1)", and/or includes anchor positions for binding to alleles of MHC class II molecules DR3 or DR4 and/or as pertains to SEQ ID NO: 19-39, has a length of at least 8 or 10 amino acids, (4) pharmaceutical compositions of all the peptides/peptide derivatives aforementioned herein.

The instant claims encompass a peptide/derivative/pharmaceutical composition, thereof consisting of between 6 and 25 amino acids which comprises at least 6 amino acid residues of one of SEQ ID NO: 2, 3 or 19-39, the said amino acid residues may not be contiguous, and which may or may not include anchor positions for binding to any allele of HLA-DR3 or HLA-DR4. The said peptide/derivative/pharmaceutical composition, thereof can comprise amino acid residues that flank the said sequences in the peptide or protein of origin, or can be any number of undisclosed and unrelated sequences, and the at least 6 amino acid residues may not be contiguous with each other in the peptide/derivative. There is insufficient disclosure in the specification on peptides of between 6 and 25 amino acids comprising at least 6 amino acid residues selected from the group consisting of Seq ID NO: 2, 3 and 19-39.

The specification discloses SEQ ID NO: 2, 3 and 19-39 (especially sequence listing and Figures 1 and 2), but no peptides or peptide derivatives of at least 6 amino acids and up to 25 amino acids from one of SEQ ID NO: 2, 3 and 19-39, other than SEQ ID NO: 4-18 which are 12-mer, 14-mer, 18-mer and 20-mer peptide subsequences derived from SEQ ID NO: 2. The specification discloses, on page 7 of the instant specification, at the last paragraph that "anchor position" means an amino acid residue essential for binding to an MHC molecule and in particular to an MHC molecule of classes DR3, DR4 or DQ. The specification further discloses at lines 8-10 of the last paragraph that the anchor positions for the DRB10401 binding motive [motif] are given in Hammer et al., Cell 74, 1993, pp 197-200.

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. However, a generic statement such as "a peptide of at least 6 amino acids of an amino acid sequence selected from the group consisting of SEQ ID NO: 2, 3 and 19-39" or "a peptide or peptide derivative having a length of 6 to 25 amino acids which exhibits a specificity or/and affinity which is essentially equivalent to that of the peptide (a) and includes anchor positions for binding to alleles of MHC class II molecules DR3 or DR4" does not describe the claimed peptide/derivative, except by the property of containing at least 6 amino acid residues from one of SEQ ID NO: 2, 3 or 19-39 or being a peptide or derivative thereof that exhibits some type or degree of specificity or/and some type or degree of affinity and includes anchor residues for binding to some undisclosed allele of HLA-DR3 or HLA-DR4. It does not specifically define any of the peptides/derivatives that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others, other than in the former case, that they comprise at least 6 amino acid residues found in one of SEQ ID NO: 2, 3 or 19-39, and in the latter case that they contain anchor residues for binding to an allele of HLA-DR3 or HLA-DR4. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. In addition, a definition by function does not suffice to define the genus because it is only an indication of what the property the peptide has, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06. It is only a definition of a useful result rather than a

definition of what achieves that result. Many such species may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

There is no disclosure of a genus of (1) peptide consisting of between 6 and 25 amino acids comprising at least 6 amino acids of an amino acid sequence selected from the group consisting of SEQ ID NO: 2, 3 and 19-39, including those wherein the peptide includes anchor positions for binding to alleles of MHC class II molecules DR3 and DR4, (2) a peptide or derivative thereof with length between 6 and 25 amino acids which exhibits a specificity or/and affinity which is essentially equivalent to that of the peptide in "(1)", and/or includes anchor positions for binding to alleles of MHC class II molecules DR3 or DR4 and/or as pertains to SEQ ID NO: 19-39, has a length of at least 8 or 10 amino acids, (4) pharmaceutical compositions of all the peptides/peptide derivatives aforementioned herein. One of ordinary skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as broadly claimed.

10. Claims 46-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and/or using a peptide with the sequence of one of SEQ ID NO: 2, 3 or 19-39, does not reasonably provide enablement for making and/or using an isolated peptide/derivative and pharmaceutical composition, thereof the: (1) peptide consisting of between 6 and 25 amino acids comprising at least 6 amino acids of an amino acid sequence selected from the group consisting of SEQ ID NO: 2, 3 and 19-39, that are not one of SEQ ID NO: 2, 3 or 19-39, including those wherein the peptide includes anchor positions for binding to alleles of MHC class II molecules DR3 and DR4, (2) peptide or derivative thereof with length between 6 and 25 amino acids which exhibits a specificity or/and affinity which is essentially equivalent to that of the peptide in "(1)", and/or includes anchor positions for binding to alleles of MHC class II molecules DR3 or DR4 and/or as pertains to SEQ ID NO: 19-39, has a length of at least 8 or 10 amino acids. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass peptides of between 6 and 25 amino acid residues in length which contain at least 6 amino acid residues, potentially in non-contiguous order, from one of SEQ ID NO: 2, 3 or 19-39 and peptides of between 6 and 25 amino acid residues in length which are comprised of undisclosed amino acid residues other than anchor residues for binding to HLA-DR3 or HLA-DR4 and which exhibit a specificity or/and affinity which is "essentially equivalent to that of the aforementioned peptides which contain at least 6 amino acid residues from SEQ ID NO: 2, 3 or 19-19. The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed invention can be made and or used. The specification does not enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification discloses SEQ ID NO: 2, 3 and 19-39 (especially sequence listing and Figures 1 and 2), but no peptides or peptide derivatives of at least 6 amino acids and up to 25 amino acids from one of SEQ ID NO: 2, 3 and 19-39, other than SEQ ID NO: 4-18 which are 12-mer, 14-mer, 18-mer and 20-mer peptide subsequences derived from SEQ ID NO: 2 (especially page 38 and sequence listing). The specification does not disclose the definition of "a specificity or/and affinity" which is "essentially equivalent to that of the aforementioned peptides which contain at least 6 amino acid residues from SEQ ID NO: 2, 3 or 19-19, and which contains anchor residues for binding to HLA-DR3 or HLA-DR4. The specification discloses the term "essentially equivalent specificity or/and affinity of binding to MHC molecules" includes an improved binding specificity or/and affinity compared to the amino acid sequences SEQ ID NO: 2, 3 or 19-39 (especially page 8 at the second full paragraph). The specification further discloses that the term peptide derivatives includes peptides in which one or several amino acid residues have been derivatized by a chemical reaction (especially page 8 at the last paragraph). The specification discloses that an object of the invention is to provide new auto-reactive peptides which react with T cells from type I diabetics, and that this object is achieved by peptides or derivatives which bind analogously which are suitable for the detection, isolation, proliferation, anergization or/and elimination of auto-reactive T cells (especially paragraph spanning pages 3 and 4). The specification discloses, on page 7 of the instant specification, at the last paragraph that "anchor position" means an amino acid residue essential for binding to an MHC molecule and in particular to an MHC molecule of classes DR3, DR4 or DQ. The specification further discloses at lines 8-10 of the last paragraph that the anchor positions for the DRB10401 binding motive [motif] are given in Hammer et al., Cell 74, 1993, pp 197-200.

Evidentiary reference Rammensee et al (Immunogenetics, 1995) teaches that peptides of between about and amino acid residues in length bind to HLA-DR3 or HLA-DR4 (especially Tables and on pages and , respectively). The length of the peptide is important for binding to HLA (along with the presence of anchor (or "motif") amino acid residues present within the peptide). An undue amount of experimentation would be involved in determining shorter peptides from the many possibilities that would be capable of binding to HLA-DR3 or DR4, and it is unpredictable if those consisting of only 6 amino acid residues would be capable of binding at all. In addition, the minimum amount of peptide required to span the binding groove and make favorable contacts may be dependent upon the sequence of the peptide itself since different amino acid residues have different physicochemical properties, and may be dependent upon the identity of the additional amino acids, since these residues may make a negative contribution to binding.

Evidentiary reference Ngo et al teaches that the relationship between the sequence of a peptide and its tertiary structure (i.e., its activity) are not well understood and are not predictable (see Ngo et al.). Accordingly, there is a high level of unpredictability in designing/selecting sequences that would still maintain function, and applicant does not provide direction or guidance to do so. Because of this lack of guidance, extended experimentation that would be required to determine which substitutions/deletions/additions or permutations of amino acids would be necessary to retain activity, and it would require undue experimentation for one of skill in the art to arrive at other amino acid sequences that would have activity. In other words, since it would require undue experimentation to identify amino acid sequences that have functional activity, it would require undue experimentation to make and use the corresponding peptides. Therefore, undue experimentation would be required to determine what peptides could or could not be used in the claimed invention.

There is insufficient guidance in the specification as to how to make and/or use the instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. The enablement provided by the specification is not commensurate with the scope of the claims. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

11. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, i.e., the disclosure on page 7 of the instant specification at lines 8-10 of the last paragraph as to the anchor positions for the DRB10401 binding motive [motif] in Hammer et al., Cell 74, 1993, pp 197-200. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 46-54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46 and 48 are indefinite in the recitation of "essentially equivalent" because it is not clear what essentially equivalent specificity or/and affinity of binding to MHC molecules is. The metes and bounds of the claimed invention are not clear.

14. With regard to application of prior art, the instant claims, in part as they pertain to SEQ ID NO: 19-39, are only entitled to priority of the instant application, i.e., 6/30/99, because the scope of the claimed invention is not disclosed in parent applications 08/967,242 and 08/374,468, and the foreign priority documents have not been provided and translated. The limitations not supported by the said parent applications is as follows: a peptide/peptide derivative/composition thereof, including comprising accessory stimulating component and B7, derived from gad having a length of at most 25 amino acids and comprising a peptide of at least 6 amino acids of an amino acid sequence selected from the group consisting of SEQ ID NO: 19-39.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 46-48 and 49-53 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/07992.

During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater , 162 USPQ 541, 550 - 51 (CCPA 1969).

WO 95/07992 teaches a 20-mer polypeptide of sequence AALGIGTDSV**ILIKCDERGK** which comprises at least 6 amino acid residues of a sequence from SEQ ID NO: 19 of the instant application, i.e., amino acid residues 1-10 of SEQ ID NO: 19. WO 95/07992 teaches the peptide linked to a label, i.e., a marker, that is a radioisotope, a lectin, a drug, or a toxin. WO 95/07992 teaches that lectins can stimulate T cells, i.e., are an accessory stimulating component. WO 95/07992 teaches pharmaceutical administration of the said peptide in pharmaceutically acceptable carrier(s). WO 95/07992 teaches that peptides from gad having at least one determinant for binding to T-cell MHC receptor can be produced or chemically synthesized (especially claims 1, 15, 18, 26 and pages 17, 18 and 27). Instant claims 46 and 48 are also included in this rejection because the recitation of "peptide derivative" "which exhibits a specificity or/and affinity which is essentially equivalent to that of the peptide" as broadly interpreted can read on the prior art.

With regard to the instant claims, the property of the peptide having anchor positions for binding to alleles of MHC class II molecules DR3 or DR4 is considered an inherent property of the reference peptide. The claimed peptide appears to be the same as the art absent a

showing of any differences. Since the Patent Office does not have the facilities for examining and comparing the molecule of the instant invention to those of the prior art, the burden is on applicant to show an unobvious distinction between the molecule of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The reference teachings anticipate the claimed invention.

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 52-54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 95/07992 in view of U.S. Patent No. 5,750,114 and U.S. Patent No. 6,060,309.

WO 95/07992 teaches a 20-mer polypeptide of sequence AALGIGTDSV**ILIKCDERGK** which comprises at least 6 amino acid residues of a sequence from SEQ ID NO: 19 of the instant application, i.e., amino acid residues 1-10 of SEQ ID NO: 19. WO 95/07992 teaches the peptide linked to a label, i.e., a marker, that is a radioisotope, a lectin, a drug, or a toxin. WO 95/07992 teaches that lectins can stimulate t cells, i.e., are an accessory stimulating component. WO 95/07992 teaches pharmaceutical administration of the said peptide in pharmaceutically acceptable carrier(s). WO 95/07992 teaches that peptides from gad having at least one determinant for binding to T-cell MHC receptor can be produced or chemically synthesized (especially claims 1, 15, 18, 26 and pages 17, 18 and 27).

WO 95/07992 does not teach a pharmaceutical composition comprising an accessory stimulating component that is a cytokine.

U.S. Patent No. 5,750,114 discloses pharmaceutical compositions comprising peptides and further comprising immunomodulators such as IL-2, i.e., a cytokine, for human administration (especially column at lines). U.S. Patent No. 5,750,114 further discloses that the choice of an adjuvant for the species of the individual being vaccinated when that species is human, depends partially upon whether or not the adjuvant has been approved for human use by the FDA

(especially column 4 at lines 23-45).

U.S. Patent No. 6,060,309 discloses administration of gad peptides along with an adjuvant, complete Freunds adjuvant (CFA), i.e., an immunomodulator (especially Example 4), to mice.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have added an adjuvant as disclosed by U.S. Patent No. 6,060,309 such as IL-2 disclosed by U.S. Patent No. 5,750,114 to the gad peptide-containing pharmaceutical composition taught by WO 95/07992.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to immunomodulate an immune response to gad peptides as disclosed by U.S. Patent No. 5,750,114 in humans because U.S. Patent No. 6,060,309 discloses administration of gad peptides along with an adjuvant CFA in mice, WO 95/07992 teaches pharmaceutical compositions comprising gad peptides for human usage and U.S. Patent No. 5,750,114 discloses pharmaceutical compositions comprising peptides and an immunomodulator such as IL-2, i.e., a cytokine, for human administration. In addition, one of ordinary skill in the art at the time the invention was made would have been aware that CFA adjuvant disclosed by U.S. Patent No. 6,060,309 was contraindicated for human usage due to the heat killed mycobacterial component in CFA.

19. No claim is allowed.

20. Upon consideration of a sequence search, SEQ ID NO. 2 and 3 are free of the prior art.

21. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
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July 23, 2001

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
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